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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,989	08/29/2006	Walter Christian Babcock	0003.0514	2581

152 7590 12/30/2008

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EXAMINER	
MENON, KRISHNAN S	
ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
12/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,989	BABCOCK ET AL.	
	Examiner	Art Unit	
	Krishnan S. Menon	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8,9 and 11-15* is/are pending in the application.

4a) Of the above claim(s) *14 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,9 and 11-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6,8,9,11-13, drawn to a process of evaluating a pharmaceutical compound.

Group II, claim(s) 14 and 15, drawn to a membrane apparatus.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the claims 1 and 14 are anticipated by the X reference cited in the PCT search report.

During a telephone conversation with Dennis Stenzel on 12/18/08 a provisional election was made with traverse to prosecute the invention of group I, claims 1-6,7,8, and 11-13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14 and 15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

It is also suggested that applicant submit the references cited in the international search report in an IDS for expediency.

Claim Rejections - 35 USC § 102/103

1. Claims 1-3, 4-6, 9, 12, and 13 rejected under 35 U.S.C. 102(b) as being anticipated by Zhu et al "A comparative study of artificial membrane permeability assay for high throughput profiling of drug absorption potential", Eur. J. Med. Chem. 37 (2002) 399-407.

This reference teaches a method of evaluating a pharmaceutical composition in a multi-plate well having hydrophilic membranes – see: "2.2. Artificial membrane permeability assay" in page 400. Feed solution is the donor solution; permeate solution is the receiving solution.

The reference uses a hydrophilic membrane, but also teaches about hydrophobic membranes as having slower permeation arte - see paragraph 3.1 on page 401.

Regarding the permeate solution, the reference does not explicitly state what it is, but it appears to be octanol from the introduction in page 399 and paragraph 2.4 in page 401.

Membrane pore size claimed is in the microporous range – and the Millipore multiwell plate used in the reference is a commercially available microporous membrane plate.

Contact angles recited are inherent in the membrane used in the reference – membrane is hydrophilic – see paragraph 2.2 at page 400. The receptor-side of this membrane is coated with lecithin in dodecane - which makes the receptor (or permeate-side) hydrophobic.

About the distribution or partition coefficients – see the table in the reference.

Aqueous solution is a phosphate buffer. Drug solubility – see the different drugs in the table.

2. Claims 1-6,8,9,11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kallury et al (US 7,468,281) and Zhu.

The teachings of Zhu are described above in the rejection paragraph 1.

Kallury teaches sample purification and analysis of drugs etc., (abstract) using multiwell plates with hydrophilized hydrophobic membranes as claimed. Liquid-liquid extraction – see column 3, lines 47-60. Microporous membranes – column 4, lines 55-67. Making the membrane surface hydrophobic or hydrophilic depends on the nature of the analyte - see column 16, lines 21-49. Choice of the solvent or permeate solution would also depend on the drug being extracted, and would be within the skill of one

ordinary skill in the art. See liquid-liquid extraction in column 3, lines 47-60 and column 8, line 66 – column 9, line 11.

It would be obvious to combine the teachings of these references to arrive at applicant's invention because such combination would result in no more than predictable results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1797